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09/251,638	02/17/1999	HENRY DANIELL	922.6641P	3456

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[REDACTED] EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	DANIELL, HENRY
09/251,638	
Examiner Anne Kubelik	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
2a) This action is FINAL. 2b) This action is non-final.
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
5) Claim(s) ____ is/are allowed.
6) Claim(s) 1-7 is/are rejected.
7) Claim(s) ____ is/are objected to.
8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). ____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) Other: ____

DETAILED ACTION

1. Claims 1-6 have been amended and claim 7 has been added, as requested by Applicant in Paper No. 10, filed 9 January, 2002. The substitute specification, the drawings, and the abstract have not been entered because Applicant did not give instructions for their entry. Claims 1-7 are pending.
2. It is noted in the substitute specification that "SEQ ID NO:2" has been inserted after mentions of "poly(GVGVP)₁₂₁", "(GVGVP)₂₀", and "(GVGVP)₁₂₁" in, for example, paragraphs [0010] and [0012]. However, SEQ ID NO:2 only is "GVGVP". All the other variants require their own SEQ ID NO:. Correction is required in reply to this Office action.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

4. The rejections of claim 6 under 35 U.S.C. 102(b) as being clearly anticipated by each of Zhang et al and Daniell et al is WITHDRAWN in light of amendment to the claim to specify that the expression cassette has a fiber-specific promoter.

Claim Objections

5. Claims 2, 4 and 7 are objected to because of the following informalities:
"SEQ. ID. NO." in claims 2 and 4 should be replaced with --SEQ ID NO:--. See MPEP 2422.03 and 37 CFR 1.821(d).

In claim 7 "an" in line 1 should be replaced with --and--.

Claim Rejections - 35 USC § 112

6. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant invention fails to teach any nucleic acids encoding GVGVP or any multimer of that polypeptide. However, the specification does refer to plasmids pBI121-X2-120mer and pBI121-E6-HW-120mer. Those particular plasmids can be enabled for the invention by deposit, as detailed below.

Since the plasmids contained in the microorganisms are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plasmids contained in the microorganisms are not so obtainable or available, a deposit of the microorganisms may satisfy the requirements of 35 USC 112. The specification does not disclose a repeatable process to obtain the plasmids contained in the microorganisms and it is not apparent if the plasmids care readily available to the public. Thus, a deposit is required for enablement purposes.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

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- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Note that such a deposit will not enable all nucleic acids encoding GVGVP or multimers of that polypeptide, nor will it enable nucleic acids encoding any elastic and plastic protein based polymer. It will only enable plasmids pBI121-X2-120mer and pBI121-E6-HW-120mer.

7. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated in the prior Office action for claims 1-2.

Applicant's arguments filed 9 January, 2002 have been fully considered but they are not persuasive. Applicant urges that Zhang et al is directed to expression of a PBP gene in tobacco cells and that they found reduced levels of PBP expression, presumably because of codon composition. Applicant urges that the instant invention proposes enhancing the level of polymer production by modifying codon composition of the gene. Applicant also urges that Zhang et al suggests supplementing the cell growth media with amino acids to overcome the low expression problem. Applicant states that the specification cites experiments that show that when tobacco transformed with GVGVP genes were selfed, the progeny formed inclusion bodies, thus supporting the assertion of successful expression in plants. Applicant urges that analysis of the chemical and physical properties of the plants is not necessary to show expression of the protein, and that analysis of these properties is well known in the art.

This is not found persuasive because the instant specification does not teach polymer-encoding DNAs wherein the DNAs have plant-preferred codons. In fact, the only DNAs mentioned in the specification that encode any polymer are plasmids pBI121-X2-120mer and pBI121-E6-HW-120mer. The expression cassettes of the instant specification, however, are drawn to those that encode any elastic and plastic polymer, of any sequence. Claims 2 and 4 are drawn to expression cassettes that encode an elastic and plastic polymer that comprises GVGVP; the claims do not specify the number of repeats of this sequence.

Analysis of the chemical and physical properties of the plants may not necessary to show expression of the protein, but it is necessary to show that fiber cells exhibit increased water absorption, fiber strength, elasticity and dye binding. With respect to the argument that analysis of these properties is well known in the art, see *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a “mere germ of an idea does not constitute [an] enabling disclosure”, and that “the specification, not the knowledge of one skilled in the art” must supply the enabling aspects of the invention. The instant specification fails to teach analysis of these properties.

The instant specification has not taught cotton plants whose fiber cells have been transformed with a DNA encoding an elastic and plastic polymer. The specification states that one method (particle bombardment) of cotton transformation requires undue experimentation to carry out (pg 6), and the other (*Agrobacterium*-mediated) can only be carried out on certain cotton cultivars. The specification fails to teach the cultivars, and the claims fail to reflect this limitation.

8. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the prior Office action for claims 1-4 and 6.

Applicant's arguments filed 9 January, 2002 have been fully considered but they are not persuasive. Applicant urges that an elastic and plastic protein polymer is one that has a repeating peptide sequence and that has elastic and plastic qualities, and that such a peptide sequence is a series of amino acid repeats. Applicant urges that the specification provides two examples, VPGVG and GVGVP. Applicant also urges that because the claims are drawn to an expression cassette, and not a gene, they differ from the situations in *Eli Lilly* and *Amgen*.

This is not found persuasive because the expression cassette comprises the gene. The coding sequence in the expression cassette is not described. Additionally, two examples of peptide repeats are not sufficient to define a broad class, and, in any case, do not provide the sequence of the DNAs that encode them.

Hence, Applicant has not, in fact, described DNA molecules that encode elastic and plastic polymers, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

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9. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 1, 3 and 6-7 are indefinite in their recitation of “elastic and plastic” as these terms are not defined in the specification.

Claim 1 is indefinite in its recitation of “dye binding capacity”. The nature of the dye is unclear, as some dyes better bind to cellulose and other better bind to protein.

Claims 2 and 4 are indefinite in their recitation of the word “repetitive”. It is not clear how many times the amino acid sequence GVGVP is repeated, or if the repetition is from the two GVs in GVGVP.

In claim 3, a promoter is driving the expression of a gene. However, a gene comprises both a coding sequence and a promoter. It is not clear how the fiber-specific promoter and the promoter of the gene are interacting.

In claim 3 it appears that the promoter is intended to drive the expression of the PBP gene, the terminator, the selectable marker gene, and the regulatory elements. It is not clear if this is what Applicant intended.

In claim 6 the nature of the manipulation and control is unclear. It is also unclear when the manipulation occurs. It is also not clear which physical and or chemical properties are being manipulated and in what manner.

Claim 6 is indefinite in its recitation of the word “synthetic”. It is not clear what aspect of the gene is synthetic, as the gene in any expression cassette would be synthesized in a heterologous organism like *E. coli* for purposes of molecular biological manipulation.

Claim 7 is indefinite in its recitation of “body temperature” as it is unclear to whose body is being referred. For purpose of examination, the body temperature of any organism was assumed.

Claim Rejections - 35 USC § 102

10. Claims 1, 3 and 5-7 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by each of John (1997, US Patent 5,602,321) and John et al (1996, Proc. Natl. Acad. Sci. USA 93:12768-12773), as stated in the prior Office action *for claims 1,3 and 5-6.*

Applicant's arguments filed 9 January, 2002 have been fully considered but they are not persuasive. Applicant urges that neither reference requires the encoded protein to be an elastic and plastic protein-based polymer and does not teach such a gene. Applicant argues that John et al is directed to a construct encoding enzymes that produce a polyester.

This is not found persuasive because the protein taught by each of John '321 and John et al (1996) would be “elastic and plastic” and would be a polymer because all proteins are polymers. John et al also refer to the protein as a “bioplastic enzyme” (column 26, line 18). This protein would unfold at a temperature below “body temperature”.

11. Claims 1, 3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by John et al (1997, US Patent 5,597,718) in light of John et al (1995, Plant Physiol. 108:669-676), as stated in the prior Office action for claims 1-3 and 5-6.

Applicant's arguments filed 9 January, 2002 have been fully considered but they are not persuasive. Applicant urges that neither John '718 nor John 1995 provide evidence that the H6

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protein is elastic or plastic, nor is there evidence that the protein would confer improved water absorption, thermal characteristics and chemical reactivity to transformed fiber cells.

This is not found persuasive because John et al (1995) teach that H6 is a humectant and glue (pg 675, left column, paragraph 2, and right column, paragraph 3); it would thus be elastic and “plastic”. John et al ('718) teach that the cotton fiber from the transformed plants have increased fiber strength (column 24, lines 3-5); the fiber cells would also have increased water absorption and elasticity (because H6 is a humectant) and increased dye binding capacity because of increased protein content. This protein would unfold a temperature below “body temperature”.

John et al '718 teach cotton plants transformed with an expression construct comprising a fiber-specific E6 promoter, the protein based polymer H6 and selectable markers (column 20, lines 31-67, column 23, line 15, to column 24, line 6, and Table 4). John et al, 1995, teach that the H6 protein contains a pentapeptide repeat (pg 675, left column, paragraph 3), and is thus a protein-based polymer. The cotton fibers from these transgenic plants have improved strength ('718, column 23, line 37, to column 24, line 6, and Table 4) and would have improved water absorption, thermal characteristics and chemical reactivity because of the presence of the H6 protein in secondary cell wall ('718, column 23, lines 22-36).

Claim Rejections - 35 USC § 103

12. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over John et al (1997, US Patent 5,597,718) in view of Zhang et al, 1996 (*supra*), as stated in the prior Office action for claims 1-6.

Applicant's arguments filed 9 January, 2002 have been fully considered but they are not persuasive. Applicant urges that this combination of references do not teach that the plant has improved properties and that one of skill in the art would not so expect the cotton to have those properties.

This is not found persuasive because John et al '718 teach the fibers from the transformed plants do have improved properties, as discussed above, and Zhang et al teaches that the polymers are superabsorbants and elastic (pg 174). Additionally, claims 3-6 are not drawn to plants but to expression cassettes. It is noted that only a reasonable expectation of success is required for determinations of obviousness, as taught in *In re O'Farrell*, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988).

13. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over John et al (1996, Proc. Natl. Acad. Sci. USA 93:12768-12773) in view of Zhang et al, 1996 (*supra*) , as stated in the prior Office action for claims 1-6.

The claims are drawn to expression cassettes comprising a fiber specific promoter and a protein based polymer gene encoding $(GVGVP)_n$ and cotton plants transformed with those cassettes.

Applicant's arguments filed 9 January, 2002 have been fully considered but they are not persuasive. Applicant urges that neither John et al nor Zhang et al teach that the presence of a plastic and elastic protein based polymer in the plant improves the properties of the plant itself.

This is not found persuasive because John et al does teach that the fibers have improved thermal properties and would have improved fiber strength, water absorption, and chemical reactivity (pg 12768, right column, paragraph1, and pg12772, right column, paragraph 2-4) and

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Zhang et al teaches that the polymers are superabsorbants and elastic (pg 174). It is noted that only a reasonable expectation of success is required for determinations of obviousness, as taught in *In re O'Farrell*, 7 USPQ 2d 1673, 1681 (Fed. Cir. 1988).

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kimberly Davis, at (703) 305-3015.

Anne R. Kubelik, Ph.D.

March 6, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

David T. Fox